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Comments of Bernard Egan & Company (BEC) on rules proposed by the Department of Health and Human Services' Food and Drug Administration (FDA) under the [U.S.] *Public Health Security and Bioterrorism PrepareBECss and Response Act of 2002 (Bioterrorism Act).*

RE: Docket No. 02N-0278 02N-0277

Bernard Egan & Company is pleased to submit these comments on the above-referenced notices of proposed rulemaking as published by the Food and Drug Administration (FDA), Department of Health and Human Services, in the Federal Register of February 3, 2003.

As the largest independently owned citrus marketer in the world, BEC imports and exports product throughout the globe. Though we are not attempting to discount the importance of the U.S. Bioterrorism Law, it is our intent to bring to light some serious concerns.

Prior Notice of Imported Food

We sincerely hope that the Secretary of Health and Human Services will have the necessary regulatory authority to implement the prior notice provisions in a way which achieves the objectives of the provisions, while at the same time taking account of the unique circumstances of produce commerce across the Canada-U.S. and Mexico-U.S. borders and the highly integrated nature of this industry.

It is our concern that the proposed provision would be detrimental to operations located within a close proximately to the U.S. border that transport extremely perishable product. Even those who are not located within a close proximity will have to make drastic and costly changes to their commercial practices; which will likely discourage U.S. buyers. It is our understanding there could be a proposal that FDA draw a representative sample of the enormous volume of trucks (and train) from Canada as part of their efforts to pin down the minimum notice time frame. We agree that this would be beneficial and also would like to suggest that sampling between sectors should be examined as well. Even a four hour proposal – which as we understand USFDA had earlier rejected – is problematic for many exporter/importers.

Quantity changes before arrival is another area of concern for BEC. We would ask that the FDA allow for the update of product quantities prior to two hours of arrival time. We had been advised that the estimated cost of the proposed rule is proportionate to the number of prior notices that will need to be changed. Due to the extreme time sensitive commercial reality, the reality of mixed loads, and greater susceptibility for substitutions due to production variables, product sizing, etc., it is our belief this will increase costs and errors caused through increased amendments. It is understood that amendments to the quantity of product arriving will impact sample sizes, however, we do not think it should be a factor in decisions on whether to interdict a shipment for bioterrorism-related reasons based on the prior notice.

We firmly believe that Canadian and Mexican fresh fruits and vegetables represent very, very low bioterrorism risk, and commercial trade is of a daily and highly repetitive nature. We sincerely hope this is considered in the final development of solutions.

In addition, it is our understanding that the FDA is proposing to require much more information than Congress intended and we hope this will be reconsidered. It would be our desire that the requirements be in line with those of the U.S. Customs Service.

As to the use of FDA Codes – It would be our desire that the USFDA be willing to accept the HS codes that are already supplied to U.S. Customs. The creation of another coding structure can only bring complexity and potential for error.

Canadian and Mexican imports by truck are our major concern. Though be it by truck, rail or aircraft, the FDA should establish times that reflect these modes and the commercial transactions involved. This approach is being promoted by the U.S. Customs service. We think it is important for the Canada-U.S. and Mexico-U.S. borders that the minimum time allowed for notice strikes the right balance between the FDA's needs and the huge volumes shipped by truck and rail. We also feel that it is also important that the requirements of the two agencies (USFDA and U.S. Customs) are as consistent as possible to avoid costly duplications and unnecessary disruptions at the Canada-U.S. and Mexico-U.S. borders.

Docket No. 02N-0277

Who can Submit a Notice

As an importer and exporter of citrus, our view is that it would be more effective for the two governments to develop mutually agreed upon criteria that their respective exporters must meet, maintain a registry that is mutually accessible to each government, and is plugged electronically into each other's customs systems. Failure to be on this list negates ability to move product into each other's country. This puts the responsibility for clearance effectively back at the greatest point of potential threat. In addition, this may reduce pressures at the border, reduce or even eliminate many of the administrative requirements which will be burdensome to non-problematic or non-threatening industry in both countries, and which in the end may not offer any real or significant guarantee of protection to the U.S. or bordering countries.

It would also mean each country would have to develop mutually agreed upon criteria as to the information needed to reassure each other of the minimization of potential threat; and also have a system for reviewing "registrants". If indeed the regulations are critical to meet U.S. and other countries' food security objectives, this alternative may replace for the majority of commerce and majority of legitimate traders, administrative obstacles which would find them unable to trade, or in a constant situation of being in violation, and consequently subject to criminal action.

This would be BEC's preference.

USFDA Proposal – The proposed rule, under Section 1.285, would require prior notice to be submitted by a purchaser or importer who resides or maintains a place of business in the United States, or an agent who resides or maintains a place of business in the United States, acting on behalf of the U.S. purchaser or importer. We think this proposal will detract from FDA

receiving the most accurate and timely information in prior notices and will cause serious adverse and unnecessary commercial consequences for exporters and their U.S. customers. If only resident U.S. parties or their agents are permitted to submit the notice, we think the FDA will be creating obstacles to its objectives.

From a commercial standpoint, if resident U.S. customers have to hire a U.S. customs broker, incur additional expenses for submitting the notice, and incur liabilities for holding products at the border, solely for purposes of the proposed rule, then a distinct competitive disadvantage will be newly introduced for exporters world wide.

Though we prefer the registration option referenced earlier, if this ultimately is not an acceptable alternative, then we would hope FDA amends the rule to include food exporters in the requirements for who must submit the notice. In addition, we would suggest the time frame for registration should be expanded beyond the 8-week period this fall.

Border Delays – There are already delays at the border. These new requirements will add further delays. Even if an exporter works to meet these, what happens if the delays are caused by U.S. Customs or border lineups? If the product deteriorates, the buyer might reject the load; or if delayed too much, cancel the order. Where does the product go then? The increase in border line-ups might also provide even more potential for tampering. One suggestion we would make would to implement a system for registering trucks at the border documenting their arrival time. Hence if a truck was delayed and could not meet the four hours allotted, there would be proof that they had indeed arrived in the necessary time. While this would add another level of administration to the border proceedings, it would never the less provide a vehicle to ensure carrier's efforts to adhere to the 4 hour window.

BEC recognizes and appreciates that the FDA officials will inform affected parties and to fully consider all comments. With the creation of new rules and extensive new information requirements this becomes even more important. Equally important will be the FDA's ability to fully automate and maintain the operation to avoid the need to revert to a paper system. Even a temporary shut down would result in unmanageable congestion at the U.S. borders.

Future Amendments – At this time, we would like to emphasize the importance and the absolute need for engagement of bilateral efforts to develop and fine tune or assess the commercial implications of the regulations. We feel it is critical that this include, USDA, US Commerce – and their Canadian counterparts – under the SmartBorder Initiative. We would go further to suggest that, at some key point, Mexico be included; the largest commerce remains between our three countries – we also share the borders (and therefore the potential threat).

Summary

This is an important initiative by USFDA to address what is sadly a reality of the times; consequently, the U.S. should be applauded for their commitment to protect their citizens from any food security threat. Not withstanding, the regulations as proposed, if implemented, will be highly disruptive to the U.S. trade, which we fully understand was never the intent. We understand that security requires new thinking and solutions.

We sincerely hope the FDA will build into the final rule, the capability to amend either regulatory requirement – registration or notification – notably in respect of imports from any country for which the FDA has reached arrangement that would serve as the basis for having different (e.g., more efficient or effective) registration or prior notice requirements. Such a provision would be important for the FDA to adjust procedures quickly and efficiently to reflect actual reductions in risks through such arrangements.

BEC appreciates the opportunity to provide our comments, and hope they are of some value in assessing the application of the proposed regulatory requirements on fresh fruit and vegetable exporters, and possible suggestions for both the development of the regulations. We sincerely hope that once the FDA has completed their review, which we would hope includes U.S. Customs and USDA, there are further bilateral discussions prior to implementation to assist the effective implementation of a system that meets U.S. needs without negating or damaging what has be an outstanding volume of non threatening trade into the U.S.

Sincerely,

David E. Mixon, Jr.
Vice President
Bernard Egan & Company